UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/978,299 | 10/15/2001 | Avi J. Ashkenazi | P2630P1C3 | 4234 |

35489 7590 06/30/2004

HELLER EHRMAN WHITE & MCAULIFFE LLP
275 MIDDLEFIELD ROAD
MENLO PARK, CO 94025-3506

| EXAMINER |
|---|
| TURNER, SHARON L |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/978,299 | ASHKENAZI ET AL. | |
| | Examiner | Art Unit | |
| | Sharon L. Turner | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *58-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4-23-02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Priority*

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e), 120 and 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicant's have amended the first line of the specification as directed in the preliminary amendment submitted 12-29-03. The amendment identifies multiple US serial numbers, PCT international applications and provisional applications. Applicant's have also submitted a supplemental communication of 6-21-02 that provides a priority map and identifies particular applications in which PRO195 (SEQ ID NO's:329-330) is allegedly disclosed. The map notes that the first disclosure is within US provisional 60/081,817. These sequences are found in this priority application. However, utility is not granted based upon activity in rat DRG survival assay and neonatal heart hypertrophy assays as set forth at pp. 361 and 348-349 of the specification. As the priority lineage does not establish compliance with the requirements of 35 USC 112, first and second paragraphs the effective filing date awarded instant claims is that of instant filing, 10-15-01.

Should the Applicant disagree with the Examiner's factual determination above, it is incumbent upon the Applicant to provide the serial number and specific page numbers of any parent application filed prior to10-15-01 which specifically supports the claim limitations for each and every claim limitation in all the pending claims which Applicant considers to have been in possession of and fully enabled for prior to 10-15-01. The utility and enablement of the invention should also be addressed as noted below.

## Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

## *Claim Rejections - 35 USC § 101 and § 112*

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 58-70 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 58-70 are directed to the protein of SEQ ID NO:330, identified as PRO195, see also Figure 132. However, the protein lacks a specific and substantial asserted utility, or a well established utility, as determined according to the current Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

The claims are directed to isolated polypeptides having at least 80% sequence identity, with or without its signal peptide, and to the extracellular domain with or

without its signal peptide. Dependent claims are directed to chimeric (containing heterologous sequences) peptides and to such peptides with an epitope tag or Fc region of an immunoglobulin. The specification contains numerous asserted utilities for the polypeptides and encoding nucleic acids, for example at pages 190-199, including use as hybridization probes, in chromosome and gene mapping, in the generation of anti-sense RNA and DNA, to identify molecules that bind to PRO (including agonists and antagonists), to make "knock-out" mice or other animals, in gene therapy, as molecular weight markers, therapeutic agents, and for the production of antibodies. The utilities that pertain solely to these nucleic acids (e.g. hybridization, chromosome and gene mapping, anti-sense) do not convey to the claimed proteins. With respect to the remaining utilities, none of these asserted utilities is specific for the disclosed PRO195 protein, as each of the aforementioned utilities could be asserted for any naturally occurring protein, and further, as none of the asserted utilities requires any feature or activity that is specific to the disclosed PRO195 molecule.

The amino acid domains of the putative PRO195 peptide are shown in Figure 132 of the specification. In particular, the peptide is noted to contain a signal peptide at amino acids 1-31, a transmembrane domain at amino acids 241-260 and an N-glycosylation site at amino acids 90-93. However there is no description of extracellular sequences or regions of the peptide.

The specification teaches at p. 361 that the PRO195 molecule tested positive in the Rat dorsal root ganglia neuronal survival inhibition assay. However, it is noted that the cultures used in this assay are of a mixed population derived from embryonic tissue.

The specification alleges that the PRO polypeptides testing positive in this assay are expected to be useful for the therapeutic treatment of neuropathic conditions associated with undesirable proliferation such as neuroblastoma, glioma or glioblastoma. Yet a search of the literature fails to reveal such correlation and there are no known exemplifications where this assay has been shown to correlate with therapeutic benefit for such diseases, see in particular Memberg et al., Mol. Cell Neurosci., 1995 Vol. 6, No. 4:323-35 and Lewis et al., J. Neurosci., 1999 Oct. 15, 19(20):8945-53. Thus, the assay fails to provide specific and substantial or well established utility.

The specification also teaches that the PRO195 molecule tested positive in the stimulation of heart neonatal hvpertrophv assav and showed activity in enhancement of heart neonatal hypertropy induced bv F2a as disclosed at pp. 348-349 of the specification. Polypeptides testing positive in these assays are supposedly useful for the therapeutic treatment of various cardiac insufficiency disorders. However, the artisan recognizes multiple heart deficiency disorders. Yet the art fails to recognize treatment of any particular heart disorder with compounds testing positive in this assay. The art recognizes multiple signal transduction pathways that regulate hearty myocyte cell growth (including hypertrophy) and gene expression, see in particular Takahashi et al., Advances in Exp. Med. & Biol., 1998, 442:129-35, Jans et al., Mol. & Cell. Biochem., Jan. 1998, 178(1-2):229-36, Oi et al., Eur. J. of Pharm., 376:139-48, 1999 and Takahashi et al., J. of Cardiovas. Pharm., 1997 Dec., 30(6):725-30. Yet the art fails to recognize therapeutic uses for any particular cardiac disease with peptide compounds that stimulate hypertrophy. In contrast, it would appear that compounds inhibiting such

stimulation would be candidates in treating cardiac hypertropy. Accordingly, this assay does not establish specific and substantial asserted utility or well established utility for PRO195 or other peptides testing positive as disclosed.

Significant further research is required of the skilled artisan to determine the function and use of the PRO195 molecule. Thus, for the aforementioned reasons, the specification fails to denote a specific and substantial asserted utility or a well established utility for the claimed polypeptides of the invention.

**Claim Rejections - 35 USC § 112**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 58-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes peptide sequence consisting of SEQ ID NO:330, which is shown to test positive in the assays noted above. However, the claims as written include polypeptides having at least 80-99% sequence identity with SEQ ID NO:330 and polypeptides including or lacking various regions including; lacking its signal peptide, the extracellular domain, the extracellular domain but lacking its signal peptide, but for which no particular biological activity or function is recited. Thus, the

claims are directed to various genus' defined solely by homology and comparison.

However, the instant disclosure of a single polypeptide, that of SEQ ID NO:330 with the instantly disclosed specific activities, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25

USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus.

However, the instant specification discloses only the single sequence and no other members of the claimed genus. Given the unpredictability of homology comparisons, see in particular Skolnick et al., Trends in Biotech., 18(1):34-39, 2000 and the fact that the specification fails to provide objective evidence of any additional sequences with the same requisite function, it cannot be established that a representative number of species have been disclosed to support the genus claim. No activity is set forth for the additional sequences and there is no evidence for a correlation or nexus provided between possession of any homologous feature and the activities as noted such that it is clearly conveyed that possession of any polypeptide having such structural similarity would possess the same function. Thus, the claims lack adequate written description support.

6. In addition to the aforementioned defects with respect to 112, first paragraph as noted above, the following deficiencies are noted even should utility be found.

7. Claims 58-70 are rejected under 35 U.S.C. 112, first paragraph, because the

specification does not reasonably provide enablement for the variable peptide sequences and for such generic sequences where no requisite functional activity is provided as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

The skilled artisan readily recognizes that protein chemistry is an unpredictable area of biotechnology. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition, see in particular Skolnick et al., Trends in Biotech., 18(1):34-39, 2000. For example, Jobling et al, Mol. Microbiol., 1991, 5(7):1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which produce proteins that differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of conserved structural components to both biological function and immunological recognition.

Instant specification discloses a single PRO195 sequence that differs from the other sequences disclosed. The specification notes that the peptide exhibits activity in the noted DRG neuronal survival inhibition assay, in the stimulation of heart neonatal

hvpertrophv and activity in enhancement of heart neonatal hypertropy induced bv F2a. However, the specification further fails to note such conserved activities in any 80-99% variable molecule. However, applicants claims are directed to peptides with 80-99% homology, to extracellular domains and to sequences lacking the signal peptide where no requisite function is required.

The specification does not enable this broad scope of the claims that encompasses a multitude of analogs or equivalents because the specification does not teach which residues can or should be modified such that the polypeptides retain sufficient structural similarity to evoke activity. The specification provides essentially no guidance as to which of the essentially infinite possible choices is likely to be successful and the skilled artisan would not necessarily expect functional conservation among homologous sequences. Moreover, no similar function is required of the additional sequences. The artisan would be unable to determine how to use such similar sequences that lack common function. The additional members would require further experimentation to discover their requisite use. Thus, applicants have not provided sufficient guidance to enable one skilled in the art to make and use the claimed derivatives in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

Thus, in view of the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims the artisan cannot make and use the invention without undue experimentation.

8. Claims 58-70 are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of ATCC 209772. Because it is not clear that cell lines possessing the properties of ATCC 209772 are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of ATCC 209772, a suitable deposit for patent purposes is required. Accordingly, filing of evidence of the reproducible production of the cell line claimed in claims 58-77 is required. Without publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

There is insufficient assurance that all required deposits have been made and all the conditions of 37 CFR § 1.801-1.809 have been met.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an

International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of the patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR § 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if the test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As a means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the ATCC 209772 cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR § 1.801-1.809 for further information concerning deposit practice.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 58-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 58-70 are directed to isolated peptides comprising "the extracellular domain" and "lacking its associated signal peptide". The specification generally teaches that the PRO "extracellular domains" are a form of the PRO polypeptide "which is essentially free of the transmembrane and cytoplasmic domains." Figure 132 teaches that PRO195 possesses a signal peptide at amino acids 1-31, a transmmmhrane domain at amino acids 241-260 and an N-glycosylation site at amino acids 90-93. However there is no description of the folded protein, extracelluar sequences or regions of the peptide. These limitations cannot be read into the claims and the specification fails to teach the orientation of the molecule with respect to the intracellular and/or extracellular portions. Further, the claim is directed to the extracellular domain lacking

its associated signal peptides. However, signal peptides are not generally considered to be "associated with" extracellular domains and indeed in this particular incidence they are not identified as being adjacent. Thus, the metes and bounds of the recitations are indefinite with respect to those residues that are intended to be included or excluded by the claim recitations and the artisan is not provided definitive guidance whereby the residues may be determined.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 58-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Furness et al., US Patent No. 6,673,549, Jan. 6, 2004.

Furness teaches genes and peptides identified as expressed in C3A liver cells when in culture with steroids. In particular, Furness teaches SEQ ID NO:818 sharing 100% identify with the peptide of instant SEQ ID NO:330. Furness teaches domains as in Table 4, column 133 including transmembrane domains at amino acids 245-265, 234-254 in addition to signal peptides at residues 1-27 and 251-266 and column 7, lines 27-36. The teachings include nucleic acids encoding the peptides, variable and homologous peptides, vectors, host cells and methods of producing the proteins

thereby, see in particular column 17-19. In particular, column 18 notes signal sequences, soluble proteins (where transmembrane regions are deleted), chimeric sequences with heterologous portions and various tags or purification facilitating domains such as metal chelating domains are co-expressed for ease of isolation and purification. Thus, the reference teachings anticipate the claimed invention.

**Status of Claims**

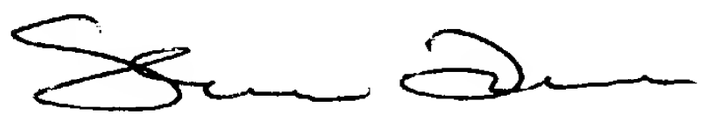
13. No claims are allowed.

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (571) 272-0887.



Sharon L. Turner, Ph.D.
June 24, 2004